

## **REMARKS**

The Office Action dated January 14, 2009, has been reviewed, and the comments of the U.S. Patent Office have been considered. Claim 30 has been amended and Claims 31-34 are indicated to be withdrawn from consideration, based on a restriction requirement not previously advanced. This amendment finds support in the application as originally filed on October 29, 2003, at page 15, lines 9 – 10.

## **RESPONSE TO THE RESTRICTION**

Applicant traverse the restriction requirement as both procedurally improper, and drawing distinction where no burden is imposed.

The Examiner has required a restriction between the following:

- I. Claims 29 and 30, drawn to the polypeptide;
- II. Claims 31 and 32, drawn to the combination of Group I and II; and
- III. Claims 33 and 34, drawn to the antibody.

The Examiner goes on to indicate that although this restriction requirement has never been presented before. “Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 31 – 34 have been withdrawn from consideration as being direct to a non-elected invention.” Office Action, page 6. While the Examiner cites MPEP §821.03 in support of this summary treatment, this section is clearly inapt.

This section deals with the situation that occurs when an applicant presents claims to a new patentably distinct invention AFTER a restriction requirement that is made final has issued. In the current application, Claims 31 – 34 were pending in their current form BEFORE this newest of restriction requirements. While Applicants have diligently pursued prosecution of this application for nearly 6 years, it seems odd now to issue, for the first time, a new restriction requirement. Still, if the Office so elects, it must give the Applicants a chance to make the election it prefers. In this case, as Applicants have previously indicated, they wish Claims 33 and 34 examined.

Notwithstanding the above, the outstanding Office Action appears to indicate that upon allowance of these claims, the remaining claims will be examined for patentability. See page 3 of the Office Action. If true, the Examiner may proceed with examination. Otherwise, Applicants respectfully elect Group III, Claims 33 and 34.

As grounds for traverse, Applicants note that for a restriction requirement to be proper, the claims must be directed to patentably distinct inventions that would impose a serious or undue burden on the Examiner to examine the claims together. MPEP 803. Examination of claims directed to an antibody to an antigen would not impose an undue burden by requiring the Examiner to perform a separate search of the prior art. Given that the antigen is being searched, it seems to be the standard of the law that the antibody would be searched as well. Similarly, examination together of claims directed to the complex of these two entities does not present an undue burden for the Examiner since a separate search of the prior art would not be required.

## **PRIORITY**

The Examiner introduces a section, page 7 of the Office Action, entitled “Priority.” It is unclear whether this is intended as an objection to the specification or a rejection of claims. It is, in any event, wrongly based, and Applicants respectfully traverse the same, to the extent it represents a substantive holding by the Examiner.

Applicants acknowledge that this application is not identical in content to the parent application filed in 1995. See the Preliminary Amendment dated October 29, 2003, the filing date of the application at issue. There is never an issue of whether the application itself is entitled to a claim of priority, the question is whether the claims are entitled to benefit of priority. To be entitled to that priority, the claims must be compared against the priority disclosure as originally filed, and that original filing must support the claims in the fashion required by 35 USC § 112, first paragraph. *Lucent Technologies, Inc. v. Gateway, Inc.*, 543 F.3s 710, 718 – 719 (Fed Cir. 2008), 88 USPQ2d 1481. (*Patent claims are awarded priority n a claim-by-claim basis based on the disclosure in the priority applications*). The Court in *Lucent* cited *GoMed Indus. Pty. Ltd. v. Inmed Corp.*, 471 F.3d 1264, 1270 (Fed. Cir, 2006) on which Applicants rely herein as well. Thus, the mere fact that the current application contains a 390 amino acid residue sequence, a sequence which is inherently the sequence of the isolated polypeptide of Example 1 of the specification as originally filed in 1995, does not impact priority if the claim does not require that 390 amino acid sequence for benefit. In fact, it does not. The Examiner’s priority analysis is respectfully submitted to be mistaken.

**REJECTIONS UNDER 35 U.S.C. § 102(B)**

Claims 29 and 30 were rejected under 35 U.S.C. § 102(b) as purportedly being anticipated by GenBank Accession No. U8213 (GenBank) and United States Patent No. 5,892,016 (Brie et al.). This rejection is respectfully traversed.

Claims 29 and 30 are drawn to subject matter disclosed, *ipsissimus verbis*, in the quite properly recited chain of priority applications, back to January 12, 1996, the filing date of great great grandparent application 08/585,758. Since this date is easily prior to the date of the references, no need exists to compare the disclosure of USSN 60/006,856 with current Claims 29 and 30. That in fact support identical to the claims exists in each of the applications whose benefit is claimed, Applicants invite the Examiner to compare Sequence 4 of U.S. Patent 5,679,523 which issued on that original 1996 filing, with the sequence that corresponds to Claims 11 – 34 of the current application. For the Examiner's convenience, that 380 amino acid residue has been highlighted in Exhibit A, submitted herewith.

As can readily be seen, the sequence of the polypeptide claimed is AMINO ACID RESIDUE FOR AMINO ACID RESIDUE IDENTICAL to sequence four initially presented in 1996. Thus, the first five residues of both sequences are Met Val Ser Lys and Tyr. The last five are Leu Ser Asp Leu and Tyr. The 245<sup>th</sup> – 249<sup>th</sup> residues of both sequences are Ala Leu Lys Arg and Thr. And so on. Each amino acid residue of the claimed sequence is identical to the residue in the same position in the benefit sequence.

The rest of the disclosure is identical as well. The example, the separation methods, etc. are all identical. In fact, as noted in the currently pending disclosure which differs from the benefit disclosure, as originally filed, in terms of sequence 4, the current sequence four is

inherently the sequence of the isolated clone of the parent application. There is nothing more inherent to a protein than its sequence of residues. Accordingly, even if *ipsis verbis* support did not exist, literally, this would be sufficient support. Kennecott Corp. v. Kyocera International, Inc., 835 F.2d 1419, 5 U.S.P.Q.2D 1194 (Fed. Cir.1987). As Applicants have properly claimed benefit of the filing date of USSN 08/585,758 which contains an enabling written description of the subject matter claimed, and has continuously since 1996 at least, the references cited are not prior art, and withdrawal of the rejection is respectfully requested. The rejections for anticipation are respectfully traversed as not in accordance with established law.

Should the Examiner elect to persist in the rejection, she is respectfully requested to point specifically to exactly what part of the claim is not supported. The sequence of amino acids identified specifically appears.

#### **OBJECTION TO THE SPECIFICATION**

The specification was objected to because it purportedly introduces new matter into the disclosure. Specifically, SEQ ID NO. 4 filed on the filing date of the instant application (October 29, 2003) has 380 amino acids but SEQ ID NO: 4 filed on June 29, 2004 has 390 amino acids. This objection is respectfully traversed.

The amino acid sequence in question was amended by preliminary amendment dated October 29, 2003. Applicants note this is the filing date of the application – by definition, no new matter was introduced. In any event, the information in the sequence is inherent in the originally filed disclosure. This information is not material to the claims, as the claims do not rely on the only difference, residues 1 – 10 of Sequence 4. Accordingly, the objection to the specification is respectfully noted, but no corrective action is perceived necessary.

**REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

Claims 29 and 30 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, SEQ ID NO:4 in Claims 29 and 30 is allegedly new matter because SEQ ID NO: 4 with 390 amino acids does not have support in the specification as originally filed. This rejection is respectfully traversed.

It is unclear what disclosure is missing from the current application. SEQ ID No. 4 is letter for letter identical to SEQ ID No. 4 submitted with this application on its original filing date. For the convenience of the Examiner, the Preliminary Amendment filed with the current application, on October 29, 2003 is submitted herewith as Exhibit B. The utility patent application transmittal for this case, the first page of Exhibit B, makes clear reference to the Preliminary Amendment. No new matter has been introduced to this application beyond that of the application as originally filed.

It is not, in any event, immediately clear how this supports a rejection for new matter. Claims 29 and 30 do not RELY on the alleged new matter, the difference between Sequence Four of the application as filed in 1996 and that as filed in 2003, the first ten amino acids of that sequence. A new matter rejection is proper only where the claim relies on the late introduced subject matter.

The claims also stand rejected because Claim 30 recites that the polypeptide in question is “free of other proteins and polypeptides.” The Examiner correctly points out that the specification as originally filed indicates it is free of other proteins and other cellular debris. While Applicants submit that one of skill in the art would have recognized that the cellular debris

would have included non-protein polypeptides, this aspect of the rejection has been mooted by amendment.

To the extent the rejection relies on new matter, it is respectfully traversed. To the extent it relies on the wording “polypeptides” it has been mooted by amendment. Withdrawal is respectfully requested.

### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this Application and the prompt allowance of at least Claims 29-34.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 10-0233. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).**

Date: April 14, 2009

Respectfully submitted,

Patent Administrator  
**Jagtiani + Gutttag, LLLP**  
10363-A Democracy Lane  
Fairfax, VA 22030  
Telephone: (703) 591-2664  
Facsimile: (703) 591-5907  
CUSTOMER NO: 22506

/Steven B. Kelber/  
Steven B. Kelber  
Attorney for Applicants  
Reg. No.: 30,073

Customer No. 22506